K003038

DEC 15 2000

510(k) Summary
(As required by 21 C.F.R. §807.92)

The submitter of this premarket notification is:	Egon Pfeil Regulatory Affairs Agilent Technologies Deutschland GmbH Herrenberger Strasse 130 D-71034 Boeblingen Germany Tel: 49 (7031) 464-7223 Fax: 49 (7031) 464-4297 Email:egon_pfeil@agilent.com
This summary was prepared on	September 22, 2000
Device name	Agilent family of Patient Monitors individually known as the M1175A/76A/77A (CMS), and M1205A (V24/26), Rev.L.
Common name	Patient Monitor

Classification names

Regulation Number	Classification Name
882.1400	Electroencephalograph

Predicate Devices

The subject device is substantially equivalent to the Aspect Medical Systems, Inc. A-2000 BIS Monitoring System marketed pursuant to K974496, and K002837, and the Agilent VueLink M1032A plug-in module cleared under K923682. Accessories are the same as those cleared for Aspect under K994330.

Modifications

The primary modification is an applications software based change that enables the Agilent patient monitors to interface with the Aspect Medical Systems, Inc. OEM BIS Engine device for the purpose of monitoring and displaying OEM BIS Engine acquired BIS data. The interface between Agilent patient monitors and the Aspect measurement set-up is the Agilent frontend link M1034A BIS Module.

Intended Use

The new device has the same intended use as the legally marketed predicate devices. For use in monitoring, recording, and alarming of multiple physiological parameters of hospitalized adult, pediatric, and neonatal patients. The devices are indicated for use in health care facilities by health care professionals whenever there is a need for monitoring the physiological parameters of adult, neonatal, and pediatric patients. The Agilent BIS System is for use in monitoring the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room, and for clinical research. The BIS, a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

Technological characteristics	The new device has the same technological characteristics as the legally marketed predicate devices.
Testing	Verification, validation, and testing activities were conducted to establish the performance and reliability characteristics of the new and modified software, and the modified interface module. Testing involved system level tests, integration tests, safety testing from hazard analysis, interference testing, and hardware testing. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Mr. Egon Pfeil
Regulatory Affairs
Agilent Technologies
Deutschland GmbH
Herrenberger Strasse 130
D-71034 Boeblingen
Germany

Re: K003038
Trade Name: Agilent Technologies CMS and V24/26 Patient Monitors with Bispectral Index (BIS™)
Regulatory Class: II
Product Code: GWQ
Dated: September 26, 2000
Received: September 29, 2000

Dear Mr. Pfeil:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K003038

Device Name The Agilent Technologies CMS and V24/26 patient monitors with BIS system, Rev.L.

Indications for Use For use in monitoring, recording, and alarming of multiple physiological parameters of hospitalized adult, pediatric, and neonatal patients. The devices are indicated for use in health care facilities by health care professionals whenever there is a need for monitoring the physiological parameters of adult, neonatal, and pediatric patients. The Agilent BIS System is for use in monitoring the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room, and for clinical research. The BIS, a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003038

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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